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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/871,564 | 05/31/2001 | Alan Collis | CA2295US-NP | 1142 |

5487 7590 04/28/2005

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EXAMINER

MORRIS, PATRICIA L

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/871,564 | Applicant(s) COLLIS ET AL. | |
| | Examiner Patricia L. Morris | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restriction

This application has been found to contain more than one invention. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to compounds, classified in classes 540, 544, 546, 548 and 549, various subclasses.
- II. Claims 16, drawn to compositions containing an additional active ingredient, classified in class 514, various subclasses.
- III. Claims 17-19, drawn to multiple uses, classified in class 514, various subclasses.

Claim 20 is an omnibus claim and cannot be grouped at this time. In the event that applicants amend the claim, it will be grouped accordingly.

These inventions are distinct, each from the other because of the following reasons:

These distinct inventions have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Accordingly, restriction for examination purposes as indicated is considered proper; 35 U.S.C. 121; 37 CFR 1.141; 37 CFR 1.142.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

Inventions I and II are unrelated because invention II does not require an additional active ingredient for the same uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In the event of an election of Group II, applicants are required to elect a single disclosed mixture. In the event of an election of Group III, applicants are required to elect a single disclosed use, *i.e.*, a specific disease.

In the event of an election of Group I, applicants are required to elect a single disclosed species representative of the claimed invention since the variations in het, R¹, R², etc., encompass all heterocyclic chemistry classified in classes 540, 544, 546, 548 and 549, various subclasses. The staggering arrangement of possibilities does not permit classification of the claimed subject matter. Each heterocycle represents an independent and patentably distinct invention.

Should applicant(s) traverse on the ground that the species inventions identified are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the above identified species inventions to be obvious variants, or clearly admit on the record that this is the case. In either instance, of traverse, if the examiner finds one of the inventions in the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

A reference to a pyrimidine here would not be a reference to a pyridine. When one writes out the entire compound, as a whole, one arrives at patentably distinct heterocyclic compounds, along the lines indicated in the Groups of the first page of this action. Distinct, independent, heterocyclic nuclei.

“A Markush-type claim is directed to “independent and distinct inventions”, if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)”. In re Weber, 198 USPQ 330, footnote 3.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

In, In re Weber, 198 USPQ 332, In re Hengehold, 169 USPQ 473, was noted for the proposition that as long as applicants have maintained the right (as they do here) to file the non-elected subject matter in divisional applications, then restriction is proper, as to that point.

Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

This restriction requirement is being written as previous experience has indicated that with Foreign applicants and the inherent time delays, applicants' representative is better able to make an informed, correct, election of the invention applicants would wish to have prosecuted here if applicants are given the opportunity to see the restriction requirement laid out, and given the time to make an informed decision.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

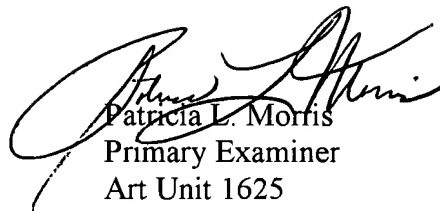
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
April 25, 2005